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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2014-0032]

Establishment-Specific Data Release Strategic Plan

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of its final Establishment-Specific Data Release Strategic Plan (the Plan) for sharing data on federally inspected meat and poultry establishments with the public. FSIS is also responding to comments received on a draft version of the Plan that FSIS posted on its Web site and announced in January 2015 in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel L. Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.) to protect the health and

welfare of consumers. The Agency is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, not adulterated, and correctly labeled and packaged.

FSIS inspects these products at official slaughtering and processing establishments, verifying that the establishments meet regulatory requirements and enforcing those requirements as necessary.

Additionally, FSIS employees (including inspectors, veterinarians, laboratorians, and Enforcement, Investigations, and Analysis Officers (EIAOs)) perform a variety of activities, including conducting inspections, ensuring compliance with existing regulations, and collecting and testing microbiological and chemical residue samples to verify that establishments are maintaining Hazard Analysis and Critical Control Point (HACCP) plans or other food safety systems that address these hazards.

While conducting these activities and performing many other key functions, FSIS collects a large volume of establishment-specific data. Using the data, FSIS produces reports for internal use, and publicly shares data and reports through the Agency's Web site¹ and other public communication venues. Most of the data that FSIS shares with the public is aggregated or in summary format; however, FSIS releases a large volume of

¹ For more information, please visit: www.fsis.usda.gov.

disaggregated, establishment-specific data to the public through formal Freedom of Information Act (FOIA) requests.²

In a notice published in the Federal Register on January 15, 2015, FSIS announced that the Agency had developed a plan for sharing data on federally inspected meat, poultry, and processed egg product establishments with the public (80 FR 2092). The Agency developed the Plan in response to policy documents issued by President Obama and the Office of Management and Budget (OMB), and to reduce the administrative burden FOIA requests have placed on the Agency.

In 2009, President Obama and OMB released policy documents that called for increased data sharing and greater transparency in Federal agencies, including President Obama's January 21, 2009 "Memorandum on Transparency and Open Government,"³ OMB's February 24, 2009 memorandum on "The President's Memorandum on Transparency and Open Government - Interagency Collaboration"⁴ and OMB's December 8, 2009 "Open Government Directive."⁵

² The Freedom of Information Act 5 U.S.C. 552, As Amended by Public Law 104-231, 110 Stat. 3048. Available at: <http://www.justice.gov/oip/amended-foia-redlined.pdf>.

³ "Transparency and Open Government: Memorandum for the Heads of Executive Departments and Agencies". (74 FR 4685; Jan. 26, 2009), pp. 4685-4686. Available at: http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment

⁴ "Memorandum for the Heads of Executive Departments and Agencies: President's Memorandum on Transparency and Open Government - Interagency Collaboration." Memorandum Number: M-09-12. 24 February, 2009. Available at: http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_fy2009/m09-12.pdf.

⁵ "Memorandum for the Heads of Executive Departments and Agencies: President's Memorandum on Transparency and Open Government - Interagency Collaboration."

President Obama subsequently issued policy documents instructing agencies to develop plans for making information on regulatory compliance and enforcement activities available in machine-readable format, and accessible, downloadable, and searchable online.⁶

Upon the recommendation of the National Advisory Committee on Meat and Poultry Inspection (NACMPI), FSIS asked the National Research Council (NRC) within the National Academies to study the potential food safety benefits and consequences of releasing establishment-specific data to the public. The NRC convened a committee in 2011 and issued a report that analyzed the costs and benefits of releasing establishment-specific data, recommending that FSIS develop a strategic plan to guide the Agency's efforts to release the data.⁷

FSIS also convened an internal committee to conduct its own in-depth review of Federal data sharing procedures and resources, which culminated in the development of the draft version of the Plan. NACMPI reviewed the draft plan in January

Memorandum Number: M-10-06. 8 December, 2009. Available at: <http://www.whitehouse.gov/open/documents/open-government-directive>.

⁶ "Memorandum on Regulatory Compliance." 76 FR 3825 (January 21, 2011); "Making Open and Machine Readable the New Default for Government Information." Executive Order 13642. 78 FR 28111 (May 14, 2013).

⁷ National Research Council, Committee on a Study of Food Safety and Other Consequences of Publishing Establishment-Specific Data. "The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data." 2011. Available at: http://www.nap.edu/catalog.php?record_id=13304.

2014 and FSIS incorporated its feedback in the announced version of the draft Plan.

Final Revision of the Plan

After carefully reviewing the submitted comments, FSIS made minor changes to the draft Plan. These changes include updated preliminary lists of datasets identified for release and considered for future release, as well as an expanded explanation of how FSIS will determine the level of aggregation for each dataset. The final revision of the Plan can be viewed on the Agency's Web site at

<http://www.fsis.usda.gov/wps/wcm/connect/0803f8a0-a3cc-4945-87b6-f992acdcfa9b/Establishment-Specific-Data-Plan-Final.pdf?MOD=AJPERES>.

The Plan establishes FSIS's process for releasing establishment-specific data on Data.gov. The Plan includes an overview of FSIS data collection processes and structures, dataset selection criteria, data release procedures, a preliminary list of Agency datasets for public release, and performance measures for evaluating the effectiveness of data release.

The preliminary list of Agency datasets for public release includes a "demographic" dataset of all regulated establishments that incorporates both information currently included in the Meat, Poultry and Egg Product Inspection Directory (name,

number, address, grant date, slaughter and/or processing, meat and/or poultry) and additional information to facilitate data analysis (e.g., variables specifically created to allow different datasets to be correctly combined). The preliminary list also includes data on Listeria monocytogenes and Salmonella in ready-to-eat (RTE) products and processed egg products; data on Shiga Toxin-producing Escherichia coli (STEC) and Salmonella in raw, non-intact beef products; data on Salmonella and Campylobacter in young chickens and young turkeys, comminuted poultry, and chicken parts; routine chemical residue testing data in meat and poultry products; and advanced meat recovery (AMR) testing data. Of these, Salmonella in raw, non-intact beef products; Listeria monocytogenes and Salmonella in processed egg products; and Salmonella and Campylobacter in young chickens and young turkeys, comminuted poultry, and chicken parts are new additions to the Plan.

Agency datasets identified for the first release include the demographic dataset and Listeria and Salmonella data in RTE products. FSIS will release these datasets by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The preliminary list of Agency datasets will not all be released at the same time, and before the release of final datasets, FSIS intends to publish a Constituent Update with a link to a sample dataset for stakeholder review. For each dataset to be released,

FSIS will determine and announce, on a case-by-case basis, the appropriate level of aggregation. For example, datasets could be aggregated at the national level or not aggregated at all, depending on FSIS's determination.

Besides the preliminary datasets that the Agency intends for release, FSIS is considering additional data sources for future release of both aggregate and individual establishment data. These include: individual establishment inspection task data associated with verification of compliance with each regulation; humane handling task data; and import sampling task data relating to STEC, Salmonella, and residue testing.

The following is a summary of the comments received and FSIS's responses.

Summary of Comments and Responses

FSIS received 19 comments in response to the January 2015 notice. The comments were from trade groups representing the meat and poultry industry, consumer groups, animal welfare groups, veterinary associations, a corporation that produces meat and poultry products, and three private citizens.

National Research Council (NRC) Study

Comment: Several commenters stated that the release of establishment-specific data could damage the reputation of product brands because consumers will relate products to the specific establishments producing those products. These

commenters suggested that the data released could create competitive disparity within the industry or cause harm to the U.S. food industry. Because of this, according to the commenters, the release of establishment-specific data would be akin to FSIS's endorsing certain brands over others.

One commenter agreed that some brands may develop an unwanted reputation based on data released to the public, but believed that this could actually benefit FSIS by weeding out bad actors.

Other commenters stated that the Plan will have a limited impact on brand reputation because consumers do not relate products to the specific establishments producing those products.

Response: While consumers could relate brands to the specific establishments producing their products, FSIS will not endorse certain brands over others through sharing data. FSIS maintains information on establishments, not brand information. When evaluating datasets for release, FSIS will thoroughly examine whether releasing datasets could have an adverse impact on the industry, including whether releasing the dataset would create market disparity. However, the NRC Committee thought that one potential benefit of releasing establishment-specific data would be that consumers would be able to make more informed choices, and that resulting consumer pressure could motivate

corporations to improve performance in order to protect brand reputation.

Criteria for Evaluating FSIS Datasets for Public Posting

Comment: Some commenters stated that data released under the Plan could contain confidential information such as Personally Identifiable Information (PII), or proprietary information such as trade secrets. Other commenters suggested that the release of certain establishment-specific data to the public could incentivize foreign countries to erect trade barriers against the United States or individual companies. One commenter noted that the release of certain establishment-specific data could expose establishments to vulnerabilities in food defense. The commenter also stated that the publication of the establishment's name, address, and size, along with the types of products produced, could direct potential terrorists to more desirable targets.

Response: FSIS will thoroughly examine candidate datasets, using multiple FSIS personnel, to ensure the datasets do not contain PII, confidential information or proprietary information. The Agency will not release data that contains confidential information, including PII, on either FSIS staff or establishment employees.

In addition, FSIS will consider potential security risks associated with release of data based on the evolving threat

landscape. The release of establishment-specific demographic data, such as the name, address, and type of product produced, does not pose a significant security risk to food defense. Most of this information is already available to the public in the Meat, Poultry, and Egg Product Directory. The Agency continues to recommend that establishments voluntarily adopt and implement food defense measures to mitigate potential vulnerabilities.

Comment: Several commenters stated that the release of disaggregated, establishment-specific data may mislead the public if there is a lack of context. For example, the public may misconstrue the meaning and significance of NRs received by establishments if the corrective actions, enforcement actions, and appeals are not also provided. These commenters worried that misinterpretation of the data could be harmful to the image of the individual establishments and the industry as a whole.

Some commenters recommended FSIS adopt a due-process mechanism to prevent the release of data that can be easily misinterpreted. These commenters requested that the industry be allowed to examine data and user guides concerning the data before they are released to the public. One commenter recommended that FSIS incorporate the user guides into the same document containing the datasets to increase the likelihood that the public will consult the guides when reviewing the data. Another commenter recommended that FSIS use consumer test panels

to evaluate whether readers understand the data. The same commenter also recommended that FSIS allow the industry to provide comments along with the datasets to help give the public some context in interpreting the data.

Response: FSIS staff will thoroughly evaluate every dataset to determine the potential for misinterpretation. If it is highly likely that the public will misinterpret the released data, the Agency will evaluate the dataset to determine if additional explanatory or contextual information would reduce that likelihood. If additional information will not reduce the potential for misinterpretation, the Agency will remove the dataset from consideration for release.

In addition, the Plan provides a thorough list of context-providing documentation that will be included in user guides with each dataset released, including: (1) a dataset overview and explanation; (2) database-specific dictionaries; (3) historical information on changes to sampling methods and scheduling or collection to inform changes to time-series; (4) the context in which the data was collected; (5) sources of variability and specificity of methods used; (6) the dataset's relationship to other released datasets; (7) data use limitations; and (8) links to analyses conducting using the data to be released. FSIS will share these user guides with industry stakeholders prior to the release of datasets to ensure the

accuracy of the information; however, there is no plan at this time to include industry comments with the released datasets.

Comment: Some commenters stated that the Plan did not articulate how the release of establishment-specific data aligns with FSIS's goals. Specifically, these commenters requested that FSIS articulate how each data release aligns with a public health objective.

Response: Every dataset released will align with the primary mission of FSIS: to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. Because of its importance, for every dataset it considers for release, FSIS will separately evaluate whether the data released will be used to benefit the public's health and reduce foodborne illness.

Comment: Some commenters expressed concern about the potential cost for the Agency to implement the Plan. One commenter stated that too many FSIS resources would be expended in implementing the Plan and requested the inclusion of additional information about cost savings.

Response: The monetary and personnel costs associated with implementing the Plan will be minimal. Under the Plan, FSIS will consider both the Agency's personnel and monetary costs when determining which datasets to release. Accordingly, data that will create a heavy administrative burden through excessive

documentation or manual redaction will not be released. To further reduce the administrative costs, FSIS will develop an automated algorithm that will identify and collect datasets intended for release.

Prioritization for Data Release

Comment: Several commenters identified additional datasets that should be considered for release, such as import inspection data, humane handling task data, Food-Safety Assessments (FSAs), codes for inspections tasks that were not performed and whether establishments participate in the new poultry inspection system.

A few commenters requested the release of information on tissue residue violations in cull dairy cows. These commenters stated that the information, which was published on the Agency's website until March 2011, is a valuable resource for the dairy industry to target outreach efforts and reduce the probability that repeat violations will occur.

Response: After considering these comments, FSIS has decided to add import inspection data, FSAs, and inspection tasks that were not performed to the preliminary list of data sources to be considered for future release. Humane handling task data is already on the preliminary list. FSA data will be limited to exclude free-text fields that may include PII or proprietary information.

FSIS announced in the 2016 Federal Register Notice titled "New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts..." that it will begin posting, based on FSIS sampling results and depending on the standard for the particular product, whether an establishment meets the FSIS pathogen reduction performance standards, or what category an establishment is in.

FSIS does not intend to resume the publication of a monthly Residue Violator List that includes the name of any producer with at least one residue violation in the previous 12-months. The Agency stopped publishing the monthly Residue Violator List in 2011 to prevent potential economic harm to producers with only one violation. Instead, FSIS will continue to publish a weekly Residue Repeat Violator List, which identifies producers with multiple residue violations within a 12-month period.⁸ FSIS notes that many first time violators do not go on to become repeat violators within the designated 12-month period. In addition, repeat violators have an incentive to improve operations and prevent violative residues in order to remove their names from the Repeat Violator List.

Comment: A few commenters requested that FSIS release

⁸ The FSIS Repeat Residue Violator List can be downloaded at <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>.

noncompliance records (NRs) filed by FSIS inspection personnel, subsequent appeals, and their eventual resolutions.

Several commenters requested that NRs not be released because consumers could easily misinterpret their significance and regulatory meaning. Those same commenters argued that it would waste FSIS resources to review and redact each NR before releasing the data.

Response: FSIS does not intend to release NRs as a stand-alone data set at this time. FSIS will consider releasing the compliance status of individual inspection tasks and regulations if FSIS decides to release inspection task data in the future. Free-text fields will never be released because of the possible presence of PII and because manual redaction is costly. However, general information, such as whether or not an NR was recorded, the date the NR was issued, which regulations it cited, whether an appeal was filed, and whether the appeal was granted, will be considered for release.

Comment: One commenter encouraged FSIS to release historical data from older data systems in addition to the Public Health Information System (PHIS) data it currently plans to release.

Response: At this time, only data collected since the implementation of PHIS in 2012 will be considered for release. The historical data from before the implementation of PHIS would

be too burdensome for the Agency to release. FSIS will consider releasing historical data from older data systems at a later date if Agency resources permit.

Data Release Procedures

Comment: One commenter asked that FSIS release data more frequently than on a quarterly basis. The commenter stated that because PHIS collects data in real time, FSIS should be able to release data every month.

Response: At this time, one new dataset from the Priority List is scheduled to be released no more frequently than on a quarterly basis. This will provide the Agency sufficient time to select and verify the accuracy of the data, as well as release a sample data set and documentation through an FSIS Constituent Update to interested stakeholders for review.

Comment: Some commenters recommended that FSIS "blind" or aggregate the datasets. The blind or aggregated data would allow interested parties to see how industry and the Agency are performing in various areas without compromising individual companies and creating market disparity.

Response: As part of the review process, FSIS will determine the most appropriate level of aggregation for each dataset. FSIS will continue to release at a national level of aggregation datasets that are currently so aggregated. For other datasets, FSIS intends to assess feedback from stakeholders and

other users of the data to determine if additional levels of aggregation would be useful. Also, for each dataset planned for initial release, FSIS plans to release establishment-specific information, including the establishment's name and number.

Measurement of Effectiveness of Data Release

Comment: One commenter stated that some of the metrics presented in the draft Plan to measure effectiveness are too narrow to fully capture the ways in which the data is used. For instance, according to the commenter, a metric for the number of presentations on related data by FSIS staff at professional meetings does not account for presentations on other topics that use the data as a portion of their presentations. Similarly, the commenter stated that a metric for the number of peer-reviewed reports generated using the establishment-specific data does not include papers that use the data that are not peer-reviewed.

Another commenter recommended that FSIS reassess the Plan after one year. If after one year FSIS determines that the data release program is not achieving its intended goals, the Agency should change the Plan.

Response: FSIS acknowledges that it is impossible to anticipate every way in which the released establishment-specific data will be used. The Plan, however, presents a framework of performance measures that will adequately inform future data releases. This framework includes a combination of

the seven quantitative metrics listed, along with qualitative measures, such as assessments of how data are interpreted and used by stakeholders. FSIS will regularly review these metrics and use them to guide future choices for data release.

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Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/federal-register>.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized

access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on July 11, 2016.

Alfred V. Almanza,

Acting Administrator.

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